Comments on the ECOFRAM Draft Aquatic Report

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I appreciate the opportunity to comment on this draft document. The working groups should be commended for their efforts.

Questions to ECOFRAM Workshop Panel Members

1. Is the draft report scientifically sound? If not, please explain and provide specific suggestions on how to improve the report to make it scientifically sound.

The scientific theory which underlies the tools and methods being proposed appears to be sound. The tiers seem to represent a logical progression from simple scenarios using basic data through increasingly complex ones using a more thorough data set. The various methods and tools discussed are aimed at reducing the uncertainty in the risk assessment.

2. Did the ECOFRAM Workgroup address the " Charge to the Terrestrial and Aquatic Workgroups" identified in the background document, " Evaluating the Ecological Risk: Developing FIFRA Probabilistic Tools and Processes" (Attachment #3)? If not, please explain why not and provide specific suggestions on how the "Charge" could be addressed.

Develop a process and tools for predicting the magnitude and probabilities of adverse effects to non-target aquatic species resulting from the introduction of pesticides into their environment.

This objective was addressed. In general, the group has provided a reasonable draft framework for the conduct of probabilistic risk assessments. The proposed approach represents a reasonable first step towards probabilistic assessments. A tiered process has been proposed and a number of tools and assessment methods are detailed.

Scientific certainty and capability for validation in a reasonable time frame.

Although based on scientific theory, the tools and models, have for the most part not been fully validated, which lessens the certainty of their results. The validation of models used to determine exposure should be achievable but the time frame will depend on the amount of resources and co-operation directed at this activity. The validation of other methods, such as population models, may take longer as the scientific understanding of ecosystem dynamics is not complete.

Solid foundation in environmental toxicology and account for species sensitivity, environmental fate and other variables.

The proposed process does attempt to account for environmental fate variables in the toxicology The approach described does not fully take into account fate and effects of transformation products, or the effects of formulants and/or formulation type on the fate and effects of products. The process only addresses the question of species sensitivity at Tier 3 which may not be adequate.

3. What are the limitations for predicting risk using the approach described in the draft report? Please provide specific suggestions.

The proposed approach is heavily dependent on the use of models and model output to describe potential exposure, and in some cases to describe toxicity or effects. Care must be taken that a false sense of certainty is not generated by the use of models and the volume of "data" from model output. Clear indications of the assumptions of models and uncertainty associated with all input and all output should be identified. All models should be validated.

The basic tier 1 screening model, GENEEC, is stated to represent a conservative scenario (i.e. a reasonable worst case), however, there needs to be some information on how conservative it really is, for example how often and under what circumstances have estimates from this model been exceeded based on monitoring data (if available), or what is the probability of a problem occurring when the screening results indicate it won't (analogous to type II error in hypothesis testing). In addition, the "one size fits all" type of scenario, i.e. climate, soil, water body definition makes it difficult to relate this to an ecologically relevant situation. Consideration should be given to adding scenarios for other regions and, as suggested in the report, for different types of aquatic systems.

For the exposure assessment, the scenarios for PRZM-EXAMS span a variety of crops and locations. Considerable effort has gone into characterizing soil, climatic parameters, and crop specific for each of the scenarios. However, in the end the same drainage area basic scenario (10 ha drainage basin and farm pond 1 ha x 2m) are used to for determination of concentrations in water. To a certain extent this results in standardized exposure concentrations and although this facilitates easy comparison between products and regions, how these exposure concentrations relate to actual exposure concentrations is a major source of uncertainty. Under the current proposal this uncertainty is carried through tier 3. The report recognizes that the type of water body used in the different scenario needs to be addressed. This needs to be done for all tiers ideally a range of water bodies, reflective of vulnerable ecosystems should be used. In the short-term some type of comparison of the "standard farm pond" with more ecological relevance could help assess the relative uncertainty.

As currently proposed the approach described does not take into account fate and effects of transformation products, or the effects of formulants and/or formulation type on the fate and effects of products. These factors can be important in determining the risk of a product to the environment and should be considered starting at the tier 2 level.

In addition, it is unclear how scale of use is or can be factored into the analyses. The

current approach seems to be directed at a single crop/single pesticide combination, where as the reality for many aquatic systems is multiple crops/multiple pesticides. At the very least some attempt needs to be made to move towards a multiple crop/single pesticide type of scenario.

As per the initial charge to the ECOFRAM group, indirect effects have not been included in the proposed framework. None the less, these types of effects can be important and need to be addressed in some manner.

There are no indications that any type of sensitivity analyses have been done with any of the models. This type of analyses could help identify what the important input parameters are, and if these correspond to some of the factors known to have major effects on the fate and/or toxicity processes.

The use of joint probability curves is a key component in bringing together exposure and toxicity in this proposed framework. The effects of various factors on JPC needs to be explored more thoroughly, for example quality of data, assumptions on underlying distributions.

The largest limitation to using and implementing the proposed approach and many of the methods/tools which are discussed within the report will be the lack of data. Although it is true that better use of data from existing toxicity tests can provide some decreases in uncertainty, as is proposed for Tier 2, the reality is that current toxicity requirements are minimal and do not adequately assess the issue of species sensitivity, nor is enough data available to conduct reasonable population analyses.

4. Taking into account your answers to the three questions above, what areas of the report need to be strengthened? If possible, please provide specific recommendations for how to strengthen the report.

a) The inclusion of the executive summary will help focus the overall report.

b) The various recommendations should be prioritized. The priorities could be divided according to major task groups:

- Models (Development/Validation)
- Data (Methods/Changed Requirements/New)
- Research
- Communications
- Education (Risk Assessors/Risk Managers)

c) The report could be strengthened by including information on the current state of efforts to validate existing models and by including a summary of results from any sensitivity analyses for the existing models.

d) The development and presentation of case studies. The current examples used in the

document (permethrin, chlorpyrifos) are not typical of the level of information usually available. Case studies with a "standard" data set from a new pesticide as well as some where additional information has been generated (eg a product which has been re-evaluated) should be presented. Although this may be beyond the scope of the current work, it will be a necessary part of any implementation.

e) The categorization of uncertainty found at the beginning of chapter 4 is most useful. It would improve comprehension if this were given earlier in the document. For each of the methods or tools or data proposed, the type(s) of uncertainty addressed and if possible the magnitude of that uncertainty should be explicitly stated. This could then be summarized in a tabular format.

f) The working group, both the exposure and effects, should give their opinion on what they see as the types of water bodies which should be used to develop scenarios.

g) Not all the assumptions made are necessarily well grounded in science. Where possible, assumptions should be referenced to peer reviewed literature.

5. At what point in the risk assessment process is the certainty level high enough to support the consideration of risk mitigation? What is the minimum level of technical information and scientific understanding that is necessary to evaluate whether risk mitigation would be necessary and/or effective?

Tier 2. The necessary level of reduction in exposure to reach "acceptability" may often be achieved through changes to application rates, frequency and/or intervals. In the cases where deterministic assessment(s) results in LOCs at or very near cutoffs or where JPCs result in borderline acceptability, these types of changes are usually explored first. If current models are validated then, changes to these types of input parameters can be assessed for their effectiveness in alleviating concern quite readily. Since these types mitigation are often proposed, it argues for the development of data on the efficacy/effectiveness of initially proposed rates of application.

The following comments were the result of an initial reading of the document. In some cases the points raised may be addressed within the document but I did not recognize. In these cases, it might indicate the need for clarification or a reference to other sections.

General Comments

In general, the document is informative and provides a reasonable draft framework for the conduct of probabilistic risk assessments. The proposed approach represents a reasonable first step towards probabilistic assessments. The working groups should be commended for their efforts.

There are some sections which are repetitive which could be condensed or referenced to other sections. The document needs a thorough editing.

The outcomes of tiers focuses on uncertainty, however at some point decision points regarding the acceptability of product need to be included. One could arguably refine an assessment to the n^{th} degree. In addition at higher tiers expert judgement plays a pivotal role in determining not only in what direction an assessment takes but in the interpretation and application of the resulting data/assessment

Care must be taken that a false sense of certainty is not generated by the use of models and model output. Clear indications of the assumptions of models and uncertainty associated with all input and all output should be identified. All models should be validated.

Currently, no consideration is given to the scope of use, i.e. a product with wide spread use on a wide variety of crops as opposed to a very narrow use on specific crop/pest.

There seems to be no consideration as to how to handle new crops/new uses as a product "matures"? Are the risk assessments modelling then re-done? If so what is the criteria for redoing a risk assessment? Should multiple uses/multiple crops be considered?

Chapter 2 - ECOFRAM Aquatic Risk Assessment Process

I agree that sediment impacts/toxicity needs to be built into future Tier 1 screening scenarios. The requirement for toxicity data should be triggered by indications that sediment partitioning will occur (e.g. Kd, Kow).

2.3.1.2 - The 3^{rd} objective will not be met under the current Tier 2 structure as a standard farm pond is being used instead of a range of aquatic ecosystems.

2.3.1.3 - pg 2-8, suggest that lab studies on environmental fate be done to reflect seasonal climactic conditions (e.g. - varying temperature for aerobic/anaerobic biotransformation studies) This would be analogous to time varying exposures on the effects side of the equation.

2.3.1.4 - Some of the proposed Tier 3 & 4 process appear to come after a regulatory decision has been made e.g. widespread monitoring, evaluation of mitigation. A distinction needs to be made as to what is feasible for the registration process, that is rendering a decision on the acceptability of a product, and what might be expected to come after a decision is made.

Detailed investigation of the efficacy of mitigation - Are mitigation efforts likely to be chemical specific or (more likely) will they be site/region/use pattern specific, in which case a task force type approach like the one used for spray drift might be a better vehicle to help characterize the validity and efficacy of various mitigation approaches?

Population modelling - Care must be exercised when using population modelling (either life history or stage/age specific) it must be recognized that additional factors can (and likely will) affect populations beyond to impacts of pesticidal effects - some margin of safety needs to be incorporated to account for these types of effects. I am curious as to how population models can be field validated since population dynamics are essentially ecosystem specific.

2.3.5 - The risk to amphibians and sediment dwelling organisms are not characterized in current tier 1 structure. Aquatic plants are only done on a cursory level (algae& lemna), there needs to be some consideration given to aquatic emergent plants. These data gaps needs to be addressed.

2.3.6.2 - The current version of GENEEC is very restrictive using only a cotton field, - how representative is this of northern states (North Dakota, Michigan, Wisconsin) which have very different climatic patterns than the current GENEEC scenario? - Agree with the later statement that tier 1 scenarios need to be developed for other crops/regions. Not sure of the uncertainty generated by use of a totally inappropriate scenario for screening.

An ELS assay is not a chronic test - it is a stage specific test, currently the only real chronic test in Tier 1 is the 21 d Daphnia test, and this does not use a sexually reproducing species.

2.3.5.4 - use of acute to chronic ratios should be limited to species in the same family group however

Table 2-2 - An explanation of why the LOCs differ between acute and chronic - this is not explicitly explained in the current text - although I suspect it has something to do with the use of peak concentrations as opposed to time weighted averages

An explanation of difference between regional and national scenario would be helpful (ie what constitutes a regional scenario, what constitutes a national scenario and how are these used to generate a JPC?).

How are uncertainties (error) associated with the JPC calculated? Could we see an example??

Will acceptable/unacceptable risk lines be the same for all products/organism groups etc.?

2.3.7.2. - Exposure Characterization at Tier 3 - Use of additional or revised environmental fate

parameters - Does this include use of end use products to determine fate input variables? - If not then this should be one of the options

How will “typical case” inputs/scenarios be developed?

Some of the tier 3 parameters (eg extent of adoption of compound) would not be available for new products.

2.3.7.3 - what scientific criteria is being used to arbitrarily set multiple exposures occurring within 1 year for fish and one month for invertebrates as the trigger for time varying or repeated exposure?

2.4 - The pair of over riding assumptions - the dominant route of exposure is going to be specific to the chemistry of the compound and the type of use being proposed for chronic exposure, a large proportion of acute exposure will be driven by water borne concentrations. If these assumptions are to be adopted some good references will be needed here.

2.5.2.1 Overview of Approaches for mitigating and managing risk - p 2-46 - the first option given is to reduce the amount of chemical applied- sub bullets a & b argue for the incorporation of efficacy trial data to ensure that optimal rates are the basis for any initial label

Considerable effort will have to be made to educate risk managers

Any proposed mitigation measures that require compliance on the part of applicators must be enforceable.

How chemical specific are the ‘Physical mitigation methods’? - like drift could/is there research currently available to indicate effectiveness of these types of mitigation measures (e.g. vegetative buffer strips for runoff)?

2.5.2 - “ a risk manager or registrant may chose to adopt mitigation to reduce the risk, even in the face of uncertainty that the mitigation will be effective” - why would a risk manager accept such a mitigative measure if there is little certainty that it would be effective?

2.6 Recommendations for improving the Overall assessment process - harmonization on an international scale will take time for the simple reason that the risk benefit basis of the FIFRA risk assessment may not be acceptable in all jurisdictions. Monitoring and/or site specific types of data may not be available at the same level of detail in all countries to allow creation of similar scenarios as proposed by ECOFRAM.

2.6.2 - Recommendations to Improve Risk characterization - Agree very much with the first recommendation on clearer identification of types of water bodies - this is necessary for all tiers. The “one size fits all farm pond” introduces too much uncertainty and its ecological relevance is not clear.

Chapter 3

Definitely agree with the recommendation on developing an approach for calculating rate constants.

Through out the document the term half-life should be replaced by the term DT50 unless it is specifically referring to results of a first-order kinetic model.

The inclusion in models the capability of handling kinetics other than first order is long - overdue. Currently the global assumption of first order kinetics for all dissipation processes is a source of great uncertainty in model input.

Current Tier 2 recommendations

In addition to wind speed, regional temperature and humidity needs to be incorporated into any probabilistic drivers for analyses of drift. I question why wind direction would be included, this to me seems very site and event specific.

The historical background is nice but I'm not sure what it adds to the "science" of the overall document.

3.4.4.1.5 - list of scenarios to use przm/exams instead of geneec - when crop of concern not adequately represented by current GENEEC scenario.

Current Tier 3 scenario still relies on the typical farm pond scenario. I question the ecological relevance of such a scenario when great efforts are made to make other inputs more relevant/realistic.

Proposed changes to aquatic metabolism studies - not sure I understand the need for this - shouldn't the model reflect reality rather than trying to have reality reflect the model??!!!

3.6.3.4 - Approaches for estimating Half-lives - if other kinetic models other than first order are adopted then 1) new criteria for persistence will have to be developed, recognizing that a biphasic pattern is common and that DT90, DT70 or MRTs may need to be used in a generalized classification scheme and 2) there is no point developing guidance on analyses if the models cannot handle input from other than first order kinetics.

3.7.5.2 Generate additional efate data to improve the understanding of exposure estimates - It was surprising that there was no discussion on the use of end use products or different formulation types to determine environmental fate input parameters at one of the higher tier levels - eg tier 3. It may be appropriate to use such studies to reduce the uncertainty with respect to partitioning/bioavailability and in some cases for rate constants. In addition use of formulated products should be required for any new tests relating to foliar dissipation, plant uptake and/or volatilization from plant surfaces as the formulants and different formulations are often designed to alter the uptake and dispersion characteristics or a product. Similar consideration should also

be

3.7.5.5.1 Landscape Analysis Approach - Although the approach is intriguing, it appears, at first glance, to be very site specific and brings up the question of what scale of scenario is appropriate for rendering a decision on the acceptability of a product. This type of analysis seems to be a step back from the proposed tier 3 where results from a range of scenarios are used to generate distributions of predicted concentrations over a regional or national scale.

Chapter 4 Ecological Effects in Aquatic Systems

4.1.1 Variability in Individual response to pesticide exposure

In addition to differences discussed in the text, for the most part laboratory tests use technical active ingredient as opposed to end use products. Different formulations can result in an alteration of the toxicity to target organisms, either directly or by altering the fate and/or distribution of the chemical in question. The inclusion of tests using end-use product formulations should be considered as possibilities for inclusion at tier 3.

4.1.4 Extrapolation from Individuals to Population-Level Endpoints - Uncertainty already exists as one extrapolates between species just for toxicity. How much uncertainty would be generated by extrapolation "population responses" from a) laboratory to field b) based on one species for another with a somewhat different life-history strategy (e.g. is a daphnia equal to a copepod)?

4.1.5 Extrapolation to Ecosystem-Level Endpoints - Just because functional redundancy exists within an ecosystem does not mean that this redundancy should be "taken advantage of" or expected to compensate for pesticide effects. Continual reliance on functional redundancy is probably not a sustainable practice - as with genetic diversity, and species diversity, once it is gone it is probably gone for good. Additionally not all ecosystems will have this redundancy, and it ignores the existence of keystone species.

4.2.2.1 Extrapolation to population-level endpoints - An additional major assumption of the time to recovery analysis is that no other impacts occur during the recovery period. With respect to pesticides the current exposure scenarios appear to consider a single crop/pesticide combination, where as in a given water shed (even small ones) there are more likely several pesticides and several crops which could increase exposure and impact on any potential recovery.

4.2.3.5 Sediment Toxicity - For sediment toxicity the assumption made, at least at Tier 1 is that organisms are only exposed to pore water concentrations. This ignores the fact that many benthic organisms consume sediment and that this represents a major route of exposure, thus the assumption is likely not valid.